UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,977	06/28/2006	Vadim Iourgenko	4-32999A	2228

1095 7590 10/29/2007

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
MACFARLANE, STACEY NEE	
ART UNIT	**PAPER NUMBER**
1649	
MAIL DATE	**DELIVERY MODE**
10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,977	IOURGENKO ET AL.	
	Examiner	Art Unit	
	Stacey MacFarlane	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-75 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-75 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-7, 11-17, in so far as they are drawn to a method to prevent/treat/ameliorate conditions comprising administering antibodies to a CREAP protein to a subject.

Group 2, claim(s) 1-6, 8, 11-15 and 18, in so far as they are drawn to a method to prevent/treat/ameliorate conditions comprising administering peptide mimetics to a CREAP protein to a subject.

Group 3, claim(s) 1-5, 9-15 and 19-20, in so far as they are drawn to a method to prevent/treat/ameliorate conditions comprising administering antisense oligonucleotides to a subject to inhibit the expression of a CREAP protein.

Group 4, claim(s) 1-5, 9-15 and 19-20, in so far as they are drawn to a method to prevent/treat/ameliorate conditions comprising administering triple helix DNA to a subject to inhibit the expression of a CREAP protein.

Group 5, claim(s) 1-5, 9-15 and 19-20, in so far as they are drawn to a method to prevent/treat/ameliorate conditions comprising administering ribozymes to a subject to inhibit the expression of a CREAP protein.

Group 6, claim(s) 1-5, 9-15 and 19-20, in so far as they are drawn to a method to prevent/treat/ameliorate conditions comprising administering RNA aptamers to a subject to inhibit the expression of a CREAP protein.

Group 7, claim(s) 1-5, 9-15 and 19-20, in so far as they are drawn to a method to prevent/treat/ameliorate conditions comprising administering double stranded RNA to a subject to inhibit the expression of a CREAP protein.

Group 8, claim(s) 1-5, 9-15 and 19-20, in so far as they are drawn to a method to prevent/treat/ameliorate conditions comprising administering single stranded RNA to a subject to inhibit the expression of a CREAP protein.

Group 9, claim(s) 21-27, drawn to a screening method to identify modulators that inhibit the activity of a CREAP protein.

Group 10, claim(s) 28-34, in so far as they are drawn to in vitro methods of screening for modulators that inhibit the expression of a CREAP protein.

Group 11, claim(s) 28-34, in so far as they are drawn to ex vivo methods of screening for modulators that inhibit the expression of a CREAP protein.

Group 12, claim(s) 28-34, in so far as they are drawn to in vivo methods of screening for modulators that inhibit the expression of a CREAP protein.

Group 13, claim(s) 35-41, in so far as they are drawn to a pharmaceutical composition comprising one or more CREAP antibodies.

Group 14, claim(s) 35-40 and 42, in so far as they are drawn to a pharmaceutical composition comprising one or more CREAP peptide.

Group 15, claim(s) 35-40, 43 and 44, in so far as they are drawn to a pharmaceutical composition comprising antisense oligonucleotides designed to inhibit the expression of a CREAP protein.

Group 16, claim(s) 35-40, 43 and 44, in so far as they are drawn to a pharmaceutical composition comprising triple helix DNA designed to inhibit the expression of a CREAP protein.

Group 17, claim(s) 35-40, 43 and 44, in so far as they are drawn to a pharmaceutical composition comprising ribozymes designed to inhibit the expression of a CREAP protein.

Group 18, claim(s) 35-40, 43 and 44, in so far as they are drawn to a pharmaceutical composition comprising RNA aptamers designed to inhibit the expression of a CREAP protein.

Group 19, claim(s) 35-40, 43 and 44, in so far as they are drawn to a pharmaceutical composition comprising double stranded RNA designed to inhibit the expression of a CREAP protein.

Group 20, claim(s) 35-40, 43 and 44, in so far as they are drawn to a pharmaceutical composition comprising single stranded RNA designed to inhibit the expression of a CREAP protein.

Group 21, claim(s) 45-46, drawn to a method of diagnosing comprising assaying mRNA levels of a CREAP protein in a biological sample.

Group 22, claim(s) 47-48, drawn to a method of diagnosing comprising assaying protein levels of a CREAP protein in a biological sample.

Group 23, claim(s) 49-53, in so far as they are drawn to a method to prevent/treat/ameliorate conditions comprising assaying CREAP mRNA and administering a CREAP modulator.

Group 24, claim(s) 49-53, in so far as they are drawn to a method to prevent/treat/ameliorate conditions comprising assaying CREAP protein levels and administering a CREAP modulator.

Group 25, claim(s) 54-55, drawn to a kit.

Group 26, claim(s) 56 and 58, drawn to an isolated polypeptide comprising a CREAP comprising of SEQ ID NOs: 2, 16 and 25.

Group 27, claim(s) 57 and 59, drawn to a nucleic acid molecule encoding a peptide comprising SEQ ID NOs: 2, 16 and 25.

Group 28, claim(s) 60, drawn to an isolated CREAP polypeptide encoded by a CREAP gene of an organism.

Group 29, claim(s) 61-64, drawn to an isolated DNA comprising a nucleic acid molecule that encodes a CREAP gene of an organism.

Group 30, claim(s) 65-68, drawn to an antibody that binds to a polypeptide comprising a CREAP comprising of SEQ ID NOs: 2, 16 and 25.

Group 31, claim(s) 69-74, drawn to a method for producing a polypeptide comprising a CREAP comprising of SEQ ID NOs: 2, 16 and 25.

Group 32, claim(s) 75, in so far as it is drawn to a vector molecule comprising a nucleic acid sequence encoding amino acids 1-267 of the human CREAP protein.

Group 33, claim(s) 75, in so far as it is drawn to a vector molecule comprising a nucleic acid sequence encoding amino acids 289-538 of the human CREAP protein.

Group 34, claim(s) 75, in so far as it is drawn to a vector molecule comprising a nucleic acid sequence encoding amino acids 575-650 of the human CREAP protein.

2. The inventions listed as Groups 1-34 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The inventions of Groups 1-8 are drawn to materially different methods of preventing/treating disease; the inventions of Groups 9-12 are drawn to screening methods with different outcomes or effects; the inventions of Groups 13-20 are each materially different pharmaceutical compositions, which are not obvious variants of one another; Groups 21-22 are drawn to methods of diagnosis but each require different methodological steps; likewise, the inventions of Groups 23-24 are drawn to methodologically different methods of treatment; the kit invention of Group 25 is structurally and /or materially distinct from the pharmaceutica products of Groups 13-20 and also materially distinct from each of the products of Groups 26-30 and 32-34. Groups 26-30 and 32-34 claim structurally different proteins, nucleic acid molecules, and antibodies. Proteins are comprise of amino acids whereas nucleic acid molecules are comprised of nucleotides. Proteins and nucleic acids have different methods and modes of use and different functions within the cell. Structurally, antibodies are unique from other proteins in that they are comprised of 4 specialized protein chains linked by disulphide bonds, as well as their functionally distinct roles within organisms. Likewise, vectors are distinct products that subserve distinct functions and mediate distinct effects within a host organism. There is nothing of record to show these different products to be obvious variants of one another.

Pursuant to 37 C.F.R. § 1.475 (a), Unity of invention before the International Searching Authority, an international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. As such, pursuant to 37 C.F.R. § 1.475 (b), the ISA/US considers that when an international or a national stage application containing claims to different categories of invention unity of invention exists if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and a process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

The inventions of Groups 1 through 34 are drawn to different products and processes that utilize structurally distinct compositions, such as proteins, nucleic acid molecules, or

antibodies. Furthermore, these inventions are patentably different categories that do not fall into one of the combinations that the ISA/US considers as supporting unity of invention.

Species Election

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

The pathological conditions of: Alzheimer's Disease, Parkinson's disease, Huntington disease, osteoarthritis, psoriasis, asthma, CORD, rheumatoid arthritis, cancer, diabetes, hypertension and chronic pain.

The structurally different proteins of CREAP1, CREAP2 or CREAP3.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 5, 15, 27, 39, and 53 relate to different pathological conditions.

Claims 6, 9, 16, 19, 22, 29, 40, 43, 46, 48 and 55 read upon structurally different CREAP proteins.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: they encompass materially different proteins and/or pathologically distinct diseases or conditions for which the methods of treatment or prevention of are not obvious variants of each other.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Effective November 1,2007, if applicant wishes to present more than 5 independent claims or more than 25 total claims in an application, applicant will be required to file an examination support document (ESD) in compliance with 37 CFR 1.265 before the first Office action on the merits (hereafter "5/25 claim threshold"). See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46715 (Aug. 21,2007), 1322 Off. Gaz. Pat. Office 76 (Sept. 11,2007) (final rule). The changes to 37 CFR 1.75(b) apply to any pending applications in which a first Office action on the merits (FAOM) has not been mailed before November 1,2007. Withdrawn claims will not be taken into account in determining whether an application exceeds the 5/25 claim threshold. For more information on the final rule, please see:

http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html

In response to the restriction requirement set forth in this Office action, applicant is required to file an election responsive to the restriction requirement. Applicant may not file a suggested restriction requirement (SRR) in lieu of an election responsive to the restriction requirement as a reply. A SRR alone will not be considered a bona-fide reply to this Office action.

If applicant elects an invention that is drawn to no more than 5 independent claims and no more than 25 total claims, applicant will not be required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims. If the elected invention is drawn to more than 5 independent claims or more than 25 total claims, applicant may file an amendment canceling a number of elected claims so that the elected invention would be drawn to no more than 5 independent claims and no more than 25 total claims.

If the restriction requirement is mailed on or after November 1, 2007, applicant is also required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims, unless the elected invention is drawn to no more than 5 independent claims and no more than 25 total claims taking into account any amendment to the claims. To avoid the abandonment of the application, the ESD (if required) and the election must be filed within TWO MONTHS from the mailing date of this Office action. The two-month time period for reply is extendable under 37 CFR 1.136.

If the restriction requirement is mailed before November 1,2007, the election must be filed within ONE MONTH or THIRTY DAYS, whichever is longer, from the

mailing date of this Office action. The time period for reply is extendable under 37 CFR 1.136. Furthermore, if the elected invention is drawn to more than 5 independent claims or more than 25 total claims taking into account any amendment to the claims, the Office will notify applicant and provide a time period in which applicant is required to file an ESD in compliance with 37 CFR 1.265 covering each of the elected claims or amend the application to contain no more than 5 independent elected claims and no more than 25 total elected claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacey MacFarlane whose telephone number is (571) 270-3057. The examiner can normally be reached on M,W and ALT. F 6 am to 3 pm, T & R 5:30 am - 4 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

/SNM/

OLGA N. CHERNYSHEV, PH.D.
PRIMARY EXAMINER